REMARKS

Amendments have been made in accordance with the requests made by the Office. The claims have been amended to read only on the elected invention. A reference to the applications from which priority is claimed has been added to the specification and the full name of the compound represented by MTP-PE has been inserted into claim 56.

Claim 56 has been amended to clarify that the subject is undergoing treatment with an anti-neoplasia agent (and a spelling error has been corrected). This amendment is for clarification as it is generally known that side effects of treatment occur simultaneously with antitumor chemotherapy. No new matter has been added and entry of the amendment is respectfully requested.

Respectfully, applicants request that correction to the Brief Description of the Drawings be deferred until formal drawings are submitted, as the necessity for designations may change depending on the pagination of the figures. With respect to the trademark Taxol, on page 5, line 10, it is believed that the specification is in conformance with the requirements since Taxol is indicated as a registered trademark already.

It is believed that the foregoing amendments and discussion dispose of the objections and formal rejections.

Claims 56 and 59 were rejected as assertedly anticipated by Kleinerman, *et al., Cancer Immunol. Immunother.* (1992) 34:211-220 or by Kleinerman, *et al., Cancer Res.* (1989) 49:4665-4670.

It is believed that the clarification to claim 56 disposes of this rejection. The desired effect of treating with MTP-PE encapsulated in liposomes is to ameliorate side effects of a concomitantly administered treatment directed against tumors. The purpose of the administration of MTP-PE is thus different from that contemplated by either Kleinerman article where the MTP-PE is itself administered as an antitumor agent. There is no actual or inherent anticipation in either case. In the paper which appeared in *Cancer Research*, as noted on page 4665, right-hand column, last partial paragraph, when the patients were administered MTP-PE, they had not received any antitumor therapy for a minimum of two weeks. Therefore, the method of the claims, as now clarified, clearly differs from the methods practiced by Kleinerman and described in the *Cancer Research* article. With respect to the article appearing in *Cancer Immunol. Immunother.*, as set forth on page 212, first paragraph in the right-hand

column, the subjects in this study did not undergo treatment with an anti-neoplasia agent at any time; they were simply treated surgically prior to attempting to elicit an antitumor response by administering MTP-PE.

Therefore, both of the Kleinerman papers describe situations in which MTP-PE is used as an antitumor agent, not as a means to treat side effects of an anti-neoplasia agent which is employed to, itself, treat the tumor. There is not even an accidental overlap since in neither Kleinerman article is the subject undergoing treatment with an anti-neoplastic agent at the time the MTP-PE is administered.

Accordingly, it is believed that claim 56 is free of the art and in a position for allowance and passage of claim 56 to issue is respectfully requested.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 204372000901.

Respectfully submitted,

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EXHIBIT A. - VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

56. (Twice amended) A method to ameliorate a side effect of anti-neoplasia treatment in a subject, wherein said side effect is [myelosupression,] mucositis [or peripheral neuropathy], which subject [has been treated] is undergoing treatment with an [anti-neoplastia] anti-neoplasia agent, which method comprises administering to said subject a pharmaceutical composition comprising muramyl tripeptide phosphatidyl ethanolamine (MTP-PE) encapsulated in multilamellar liposomes.